

Anti-Infective Drugs Advisory Committee Meeting

June 2, 2009

NDA 22-398

Cethromycin

Advanced Life Sciences

Hilton/Silver Spring, Maryland

Meeting Roster

ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Thomas Moore, M.D., FACP (Chair)

Clinical Professor

Department of Medicine

University of Kansas School of Medicine

Wichita, KS

W. Kemper Alston, M.D., M.P.H.

Professor of Medicine

Infectious Diseases Unit

Fletcher Allen Health Care

University of Vermont College of Medicine

Burlington, VT

Dean Follmann, Ph.D.

Assistant Director for Biostatistics

National Institute of Allergy and Infectious Diseases

Bethesda, MD

Matthew Bidwell Goetz, M.D.

Professor of Clinical Medicine

David Geffen School of Medicine at UCLA

Chief, Infectious Diseases Section

VA Greater Los Angeles Healthcare System

Los Angeles, CA

Sheldon Kaplan, M.D.

Professor and Vice-Chairman for Clinical Affairs

Head, Section of Pediatric Infectious Diseases

Department of Pediatrics

Baylor College of Medicine

Chief, Infectious Disease Service

Texas Children's Hospital

Houston, TX

Peter Katona, M.D.

Associate Professor of Clinical Medicine

David Geffen School of Medicine at UCLA

Los Angeles, CA

Carol Kauffman, M.D.

Professor, Infectious Diseases Section

Veterans Affairs Healthcare System

Ann Arbor, MI

Kent A Sepkowitz, M.D.

Vice Chairman, Clinical Affairs

Director, Hospital Infection Control

Memorial Sloan-Kettering Cancer Center

New York, NY

Margo Smith, M.D.

Director, Infectious Diseases

Washington Hospital Center

Washington, D.C.

Melvin P. Weinstein, M.D.

Professor of Medicine and Pathology

Chief, Division of Infectious Diseases, Allergy & Immunology

UMDNJ-Robert Wood Johnson Medical School

Director, Microbiology Laboratory

Robert Wood Johnson University Hospital

New Brunswick, N.J

Annie Wong-Beringer, Pharm.D. (Consumer Rep.)

Associate Professor of Pharmacy

University of Southern California

School of Pharmacy

Los Angeles, CA

INDUSTRY REPRESENTATIVE (Non-Voting)

John H. Rex, M.D., F.A.C.P.

Infection Clinical Vice President

AstraZeneca; Alderley House

United Kingdom

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TEMPORARY VOTING MEMBERS

William J. Calhoun, M.D., F.A.C.P.

Sealy and Smith Distinguished Professor of Internal
Medicine

University of Texas Medical Branch
Galveston, Texas

Thomas Fleming, Ph.D.

Professor of Biostatistics

University of Washington
Seattle, Washington

Gregory Townsend, M.D.

Associate Professor

Division of Infectious Diseases

Department of Internal Medicine

University of Virginia Health Systems
Charlottesville, Virginia

FDA PARTICIPANTS (Non-Voting)

Edward Cox, M.D., M.P.H.

Director

Office of Antimicrobial Products

Katherine Laessig, M.D.

Deputy Director

Division of Anti-infective and Ophthalmology Products
Office of Antimicrobial Products

Nasim Moledina, M.D.

Medical Officer

Division of Anti-infective and Ophthalmology Products
Office of Antimicrobial Products

John Alexander, M.D., M.P.H.

Medical Team Leader

Division of Anti-infective and Ophthalmology Products
Office of Antimicrobial Products

Christopher Kadoorie, Ph.D.

Statistical Reviewer

Division of Biometrics IV

Office of Biostatistics

Thamban Valappil, Ph.D.

Statistical Team Leader

Division of Biometrics IV

Office of Biostatistics